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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities; Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Project: Notification of Intent to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction Under 21 U.S.C. 823(g)(2) (OMB No. 0930–0234) – Extension

The Drug Addiction Treatment Act of 2000 (“DATA,” Pub. L. 106–310) amended the Controlled Substances Act (21 U.S.C. 823(g)(2)) to permit practitioners (physicians) to seek and obtain waivers to prescribe certain approved narcotic treatment drugs for the treatment of opiate addiction. The legislation sets eligibility requirements and certification requirements as well as an interagency notification review process for physicians who seek waivers. The legislation was amended in 2005 to eliminate the patient limit for physicians in group practices, and in 2006, to permit certain physicians to treat up to 100 patients.

To implement these provisions, SAMHSA developed a notification form (SMA-167) that facilitates the submission and review of notifications. The form provides the information necessary to determine whether practitioners (i.e., independent physicians) meet the

qualifications for waivers set forth under the new law. Use of this form will enable physicians to know they have provided all information needed to determine whether practitioners are eligible for a waiver.

However, there is no prohibition on use of other means to provide requisite information. The Secretary will convey notification information and determinations to the Drug Enforcement Administration (DEA), which will assign an identification number to qualifying practitioners; this number will be included in the practitioner's registration under 21 U.S.C. 823(f).

Practitioners may use the form for three types of notification: (a) new, (b) immediate, and (c) to notify of their intent to treat up to 100 patients. Under "new" notifications, practitioners may make their initial waiver requests to SAMHSA. "Immediate" notifications inform SAMHSA and the Attorney General of a practitioner's intent to prescribe immediately to facilitate the treatment of an individual (one) patient under 21 U.S.C. 823(g)(2)(E)(ii). Finally, the form may be used by physicians with waivers to certify their need and intent to treat up to 100 patients.

The form collects data on the following items: Practitioner name; state medical license number and DEA registration number; address of primary location, telephone and fax numbers; e-mail address; name and address of group practice; group practice employer identification number; names and DEA registration numbers of group practitioners; purpose of notification new, immediate, or renewal; certification of qualifying criteria for treatment and management of opiate dependent patients; certification of capacity to refer patients for appropriate counseling and other appropriate ancillary services; certification of maximum patient load, certification to use only those drug products that meet the criteria in the law. The form also notifies practitioners of Privacy Act considerations, and permits practitioners to expressly consent to

disclose limited information to the **SAMHSA Buprenorphine Physician Locator**.

Since July 2002, SAMHSA has received over 25,000 notifications and has certified almost 27,000 physicians. Fifty-nine percent of the notifications were submitted by mail or by facsimile, with approximately forty-one percent submitted through the Web based online system. Approximately 60 percent of the certified physicians have consented to disclosure on the **SAMHSA Buprenorphine Physician Locator**.

Respondents may submit the form electronically, through a dedicated Web page that SAMHSA will establish for the purpose, as well as via U.S. mail.

There are no changes to the forms and burden hours.

The following table summarizes the estimated annual burden for the use of this form.

Purpose of Submission	Number of Respondents	Responses per Respondent	Burden per response (hr.)	Total Burden (hrs)
Initial Application for Waiver	1,500	1	.083	125
Notification to Prescribe Immediately	50	1	.083	4
Notice to Treat up to 100 patients	500	1	.040	20
Total	2,050	-----	-----	149

Written comments and recommendations concerning the proposed information collection should be sent by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs,

Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via e-mail to:

OIRA_Submission@omb.eop.gov. Although commenters are encouraged to send their comments via e-mail, commenters may also fax their comments to: 202-395-7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, D.C. 20503.

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